K053478

APR 5 2006

510(k) Premarket Notification Summary

Name/Address of Submitter: Northern Implants, LLC
10355 B Democracy Lane
Fairfax, VA 22030

Establishment Registration Number: 3003845138

Contact Person: Greta M. Hols
Phone: (703) 278-3953
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Date Summary Prepared: December 1, 2005

Device Classification Name: Endosseous Implant and Accessories

Device Classification Regulation Number: 21 CFR 872.3640 and 21 CFR 872.3630

Device Regulatory Status: Class II Special Controls

Trade Name: Endosseous Dental Implant

Purpose: The purpose of this 510(k) is to include additional implants and accessories in the NSI Hexed and Non-Hexed Endosseous Implant System that did not fall within the size range and design shapes identified in prior 510(k) submissions for our system.

Performance Standards: FDA has not established a performance standard applicable to endosseous implants and their accessories. The materials in the NSI Hexed Implant System meet applicable voluntary standards. Northern Implant's screw-type implants and abutments are manufactured from ASTM F67-95 Grade III or Grade IV Titanium.

Predicate Devices: K003620 NSI Hexed and Non-Hexed Implant System
K020617 NSI Hexed and Non-Hexed Implant System
K954347 Implant Innovations 3.25mm microminiplant

Device Description and Intended Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Sterilization Methods Used: Sterilization of these implants will be achieved using Co60 irradiation, with a minimum dose of 25.0 kGy (2.5 m rads), creating a Sterility Assurance Level of 10^{-6}. Validation of sterilization will be done as specified by the Association for the Advancement of Medical Instrumentation (AAMI). Standards utilized include:

ISO 11137	Sterilization of Health Care Products – Requirements for validation and routine control – Radiation sterilization
ISO 11737-2	Sterilization of Medical Devices – Microbial Methods – Part 2: Tests of sterility performed in the validation of a sterilization process
ISO 13409	Sterilization of Health Care Products – Radiation Sterilization – substantiation of 25kGy as a sterilization dose for small or infrequent production batches.

Packaging Validation:

Validation protocols followed the following standards:

ASTM D 4169-04	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F 88-00	Standard Test Method for Seal strength of Flexible Barrier Materials
ASTM F 1929-98	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ISO 11607	Packaging for terminally sterilized medical devices

Technological Characteristics: The physical properties and designs of the additional implants and accessories in the NSI Hexed and Non-Hexed Implant System were compared with legally marketed predicate devices. The technological characteristics were comparable.

Brief Discussion of Clinical Studies: Clinical studies were not conducted, or deemed necessary, for the purpose of this 510(k) submission.

Conclusions Drawn: The NSI Hexed and Non-Hexed Implant System has the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Any differences in the technological characteristics did not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2006

Ms. Greta M. Hols
Northern Implants, Limited Liability Company
10355 B Democracy Lane
Fairfax, Virginia 22030

Re: K053478
Trade/Device Name: Endosseous Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endossesous dental implant
Regulatory Class: II
Product Code: DZE
Dated: March 23, 2006
Received: March 31, 2006

Dear Ms. Hols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

Indication for Use

510(k) Number: K053478

Device Name: Endosseous Dental Implant System

Indication for Use: The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ OR Over-the-counter Use _____.

(Per 21 CFR801.109)

Susan Runner

...ology, General Hospital,
...Dental Devices

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